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Licata & Tyrrell P.C.

66 E. Main Street Marlton, New Jersey

Tel: (856) 810-1515 Fax: (856) 810-1454

November 3, 2003

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TO: Examiner Wilder (TC1600)

**GROUP: 1637** 

FAX NUMBER: 703-872-9306

ATTORNEY DOCKET NO.: DEX-0249

SERIAL NO.: 10/082,830

FILED: October 29, 2001

**NUMBER OF PAGES:** 

MESSAGE: Attached please find Amendment Transmittal Letter, Reply to Restriction Requirement and Certificate of Transmission by Facsimile.

Kathleen A. Tyrrell, Registration No. 38,350

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	SIMULE (37 CFR 1.8)	Docket No.							
Applicant(s): Sun et al.			DEX-0249						
Serial No. 10/082,830	Filing Date October 29, 2001	Examiner Wilder, Cynthia B.	Group Art Unit						
Invention: Compositions and Methods Relating to Breast Specific Genes and Proteins									
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AMENDMENT TRANSMITTAL LETTER (Large Entity) Applicant(s): Sun et al.						Docket No. DEX-0249				
		ng Date er 29, 2001	l`	Examiner Wilder, Cynthia B.		Group Art Unit 1637				
Invention: Compositions and Methods Relating to Breast Specific Genes and Proteins										
TO THE COMMISSIONER FOR PATENTS:  Transmitted herewith is an amendment in the above-identified application.										
The fee has been	The fee has been calculated and is transmitted as shown below.									
		CLAIMS A	S AMENDED	)		· · · · · · · · · · · · · · · · · · ·				
	CLAIMS REMAINING	HIGHEST #	NUMBE	ER EXTRA	RATE	I	ADDITIONAL			
	AFTER AMENDMENT	PREV. PAID FOR		PRESENT		- 20	FEE			
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<ul> <li>No additional fee is required for amendment.</li> <li>□ Please charge Deposit Account No. in the amount of</li> <li>□ A check in the amount of to cover the filing fee is enclosed.</li> <li>☒ The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No.</li> <li>☒ Any additional filing fees required under 37 C.F.R. 1.16.</li> <li>☒ Any patent application processing fees under 37 CFR 1.17.</li> </ul>										
Mathle A. Tyrrell, Reg. No. 38,350  Dated: November 3, 2003  Kathleen A. Tyrrell, Reg. No. 38,350										
Mariton, New Jersey 08053   Tel: 856-810-1515					I certify that this document and fee is being deposited on with the U.S. Postal Service as first class mall under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.					
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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

NOV 0 3 2003

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Attorney Docket No.:

DEX-0249

Inventors:

Sun et al.

Serial No.:

10/082,830

Filing Date:

October 29, 2001

Examiner:

Wilder, Cynthia B.

Group Art Unit:

1637

Title:

Compositions and Methods Relating to Breast Specific Genes and Proteins

#### Certificate of Facsimile Transmission

I hereby certify that this document is being facsimite transmitted to the Patent and Trademark Office on the date shown below.

On November 3, 2003

Cathleen A. Tyrrell, Registration No. 38 350

Mail Stop

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

## Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed October 2, 2003 setting a one (1) month statutory period for response. Please enter the following remarks into the record.

Remarks begin at page 2.

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October 29, 2001 Filing Date:

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#### REMARKS

Claims 1-17 are pending in the instant patent application. Claims 1-17 have been subjected to a Restriction Requirement as follows:

Group I, claims 1-5, 7-9, and 15, drawn to an isolated nucleic acid, classified in class 536, subclass 23.1;

Group II, claims 6 and 14, drawn to a hybridization method for determining the presence of breast specific nucleic acid (BSNA), classified in class 435, subclass 6;

Group III, claim 10, 11 and 15, drawn to an isolated polypeptide, classified in class 530, subclass 350;

Group IV, claims 12, drawn to an antibody, classified in class 424, subclass 130.1;

Group V, claims 12, 14, drawn to a protein binding assay for determining the presence of breast specific nucleic acid, classified in class 435, subclass 7.1;

Group VI, claim 16, drawn to a method of treating a patient with drug, classified in class 514, subclass 12; and

Group VII, claim 17, drawn to a vaccine, classified in class 424, subclass 184.1.

The Examiner suggests that these Groups are distinct, each

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Inventors:

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from the other.

Specifically, with respect to Groups I, III, IV and VII, the Examiner suggests that the claims of these Groups are drawn to unrelated products.

With respect to Groups I and II, IV and Groups III, IV and V, VI, the Examiner has acknowledged their relationships as product and process of use. However, the Examiner suggests that these Groups are distinct because the products can be used in materially different processes.

With respect to Groups II, V and VI, the Examiner suggests that the Groups are unrelated methods.

Further, the Examiner suggests that each of the above Groups reads on patentably distinct sequences and has requested that Applicants further elect a single amino acid of single nucleic acid sequence.

At the outset, clarification is requested with respect to claims encompassed in Group V. The Examiner suggests that Group V, claims 12, 14 are drawn to a protein binding assay. respectfully pointed out, however, that neither of these claims are drawn to this subject matter. Further, claims 12 and 14 were included in Groups IV and II, respectively. Applicants believe that the Examiner meant to include only claim 13 in Group V.

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However, clarification of the record by the Examiner is respectfully requested.

Further, Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody. Accordingly, Applicants believe that searching of all the claims, at least when limited to elected nucleic acids, polypeptides, or antibodies, is overlapping and would not place an undue burden on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP \$ 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

In addition, with respect to the election of a single sequence, MPEP \$ 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed Attorney Docket No.: DEX-0249

Inventors:

Sun et al.

Serial No.:

10/082,830

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October 29, 2001

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in a single application. Accordingly, withdrawal of this sequence election requirement and reconsideration to include a more reasonable number of at least 10 sequences in accordance with MPEP § 803.04 is also respectfully requested.

However, in an earnest effort to advance the prosecution of this case Applicants elect Group I, claims 1-5, 7-9 and 15 with traverse. Further, Applicants elect SEQ ID NO:99 encoding SEQ ID NO:224, with traverse. Since SEQ ID NO:98 is a sub-sequence of SEQ ID NO: 99, it is respectfully requested that at least SEQ ID NO:98 be included in this case as well.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

Date: November 3, 2003

LICATA & TYRRELL P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515